

determine, what portion of its contribution is applicable to health benefits.

(f) *Retention and availability of data.* Each employing entity or designee must retain the following data for three years and make it available to HCFA upon request:

(1) The data used to compute the level of contribution for each of the plans offered to employees.

(2) Related data about the employees who are eligible to enroll in a plan.

(3) A description of the methodology for computation.

(g) *HCFA review of data.* (1) HCFA may request and review the data specified in paragraph (f) of this section on its own initiative or in response to requests from HMOs or employees.

(2) The purpose of HCFA's review is to determine whether the methodology and the level of contribution comply with the requirements of this subpart.

(3) HMOs and employees that request HCFA to review must set forth reasonable grounds for making the request.

[61 FR 27287, May 31, 1996]

#### **§ 417.158 Payroll deductions.**

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

[59 FR 49841, Sept. 30, 1994]

#### **§ 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.**

The decision of an employing entity subject to this subpart to include the HMO alternative in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

[59 FR 49841, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

### **Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations**

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

#### **§ 417.160 Applicability.**

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

[59 FR 49841, Sept. 30, 1994]

#### **§ 417.161 Compliance with assurances.**

Any entity subject to this subpart must comply with the assurances that it provided to HCFA, unless compliance is waived under § 417.166.

[58 FR 38071, July 15, 1993]

#### **§ 417.162 Reporting requirements.**

Entities subject to this subpart must submit:

(a) The reports that may be required by HCFA under § 417.126, and

(b) Any additional reports HCFA may reasonably require.

[58 FR 38071, July 15, 1993]

#### **§ 417.163 Enforcement procedures.**

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with HCFA a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

(1) State the grounds and underlying facts of the complaint;

(2) Give the names of all persons involved; and

(3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) HCFA may initiate investigations when, based on a report, a complaint, or any other information, HCFA has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When HCFA initiates an investigation, it gives the HMO written notice that includes a full statement of

the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) HCFA obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that HCFA considers appropriate in seeking this information.

(c) *Determination and notice by HCFA*—(1) *Determination*. (i) On the basis of the investigation, HCFA determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) HCFA publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action*. (i) HCFA gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that HCFA considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from HCFA, or within any longer period that HCFA determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by HCFA in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for HCFA's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification*. If HCFA determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—

(1) HCFA revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, HCFA provides the HMO with an opportunity for reconsideration of the revocation, including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day after the day of the notice unless HCFA receives a request for reconsideration by that date.

(4) If after reconsideration HCFA again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) HCFA publishes in the FEDERAL REGISTER each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in §417.164.

(e) *Notice by the HMO*. Within 15 days after the date HCFA issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed*. (1) If HCFA determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, HCFA may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§417.104 and 417.105. The additional rules applicable to Medicare enrollees are in §415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability*. This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding

the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If HCFA determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, HCFA may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

**§ 417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.**

When an HMO's qualification is revoked under § 417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

**§ 417.165 Reapplication for qualification.**

An entity whose qualification as an HMO has been revoked by HCFA for purposes of section 1310 of the PHS Act may, after completing the corrective action required under § 417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

**§ 417.166 Waiver of assurances.**

(a) *General rule.* HCFA may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which HCFA may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If HCFA waives any assurances regarding compliance with section 1301 of the PHS Act, HCFA concurrently revokes the HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

**Subpart G—I—[Reserved]**

**Subpart J—Qualifying Conditions for Medicare Contracts**

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

**§ 417.400 Basis and scope.**

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with HCFA to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with HCFA under section 1876 of the Act. It also specifies the procedures that HCFA follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.